

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF WEST VIRGINIA  
AT CHARLESTON**

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| <b>IN RE: ETHICON, INC., PELVIC<br/>REPAIR SYSTEM PRODUCTS<br/>LIABILITY LITIGATION</b> | <b>Master File No. 2:12-MD-02327<br/>MDL No. 2327</b> |
| <b>THIS DOCUMENT RELATES TO<br/>ALL CASES</b>   | <b>JOSEPH R. GOODWIN<br/>U.S. DISTRICT JUDGE</b>      |

**DEFENDANT ETHICON, INC.'S OPPOSITION TO PLAINTIFFS' MOTION TO  
COMPEL**

Plaintiffs' Motion to Compel reads in part as if it were written for another lawsuit. It all but ignores the work of both parties over the past year, fails to mention critical facts, and contains some statements that are just not true. In particular, one can read it and never know that:

- Approximately 8.5 million pages of documents have been produced in an electronic format *that was agreed to by* plaintiffs. The purpose of that format was to obviate the types of issues plaintiffs are raising in this motion by providing plaintiffs with a "directory" of plaintiffs' counsels' own design;
- Ethicon has produced well over a million pages of documents from foreign countries, including all worldwide adverse event reports. Ethicon's search efforts for other materials covered more than 32 countries;
- Ethicon long ago provided an attorney-client and work product privilege log which now totals more than 18,000 entries;
- Ethicon has provided plaintiffs with a listing of more than 800 company procedures, produced 171 of those that the plaintiffs requested, and offered to work with plaintiffs and their technical experts to select from an estimated 98,000 policy and procedure documents, with 500,000 revisions; and

- In the spirit of compromise, Ethicon has supplemented its discovery responses in an effort to address many of plaintiffs' concerns and has offered to meet and confer to address others, but plaintiffs refuse to engage in a meaningful meet and confer to address specific issues. Rather, they continue to take the unreasonable position that *all* of Ethicon's objections should be overruled in the abstract.

Ethicon respectfully submits that the motion to compel should be denied. Alternatively, the parties should be ordered to continue to meet and confer to resolve these issues without additional Court intervention.

### **ARGUMENT**

The motion to compel has the argument backwards. Its highly abstract format would make some sense if the plaintiffs had no basis for being more specific about what they believe they have been denied and why it is relevant to this case. But this case has the New Jersey litigation which began in 2008 as a preface, and in the light of that preface it is the lack of specificity in the motion, not the lack of specificity in the objections, that is the real problem with discovery in this case. The truth is that millions of pages of indexed documents have been produced, yet the plaintiffs in their motion have not given even one example of specific evidence that they believe has been kept from them.

Some background may be helpful to an understanding of the issue.

At the outset of this MDL, this Court asked and Ethicon agreed to provide the plaintiffs with all discovery produced in the New Jersey state court consolidated litigation. This included millions of pages of documents, numerous deposition transcripts, and Ethicon's discovery responses. These documents were produced as they are maintained, in an electronically-searchable format, pursuant to an exhaustively negotiated ESI protocol. *See* Pre-Trial Order #13, Ex. A. Plaintiffs included their own technical consultants in the negotiations.

Pursuant to this stipulated protocol, these documents were produced accompanied with electronic data provided in the specific searchable format with at least 30 agreed-upon index

fields, including custodian, document type, email subject, names of attachments, author and file path to source files. *Id.*<sup>1</sup> Even though they had this discovery in hand, plaintiffs nevertheless propounded 122 requests for production and more than 22 interrogatories, which include in excess of 90 subparts.<sup>2</sup> Even after steering committee members assisted in the prosecution of a case against Ethicon tried in New Jersey for six weeks, plaintiffs made no effort to narrow their requests to clarify what – if anything – they were seeking that had not already been produced to them. Ethicon responded and after discussions with plaintiffs, submitted Supplemental Responses removing some of its objections.

### **I. Ethicon Has Not Waived Its “Subject To” Objections**

As a general rule, Ethicon has responded to discovery requests “subject to” its objections because it does not understand what is being requested and not because it is affirmatively withholding documents based on its objections. There are certain exceptions, e.g., documents related to hernia mesh devices which are not at issue in this motion and certain foreign documents discussed below. Ethicon has offered to meet with plaintiffs to address its objections.

Ethicon’s discovery responses repeatedly explain that its “subject to” objections mean that it objects to discovery having to do with hernia mesh products, foreign regulations, and foreign entities. *See* Ex. B. To alleviate any remaining uncertainty, Ethicon has offered to meet and confer with plaintiffs’ counsel concerning each and every “subject to” objection. That offer has been refused. *See* Ex. C. If that offer had been accepted, there would be absolutely no problem in this case with what this Court has called “doubting the thoroughness and implication

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<sup>1</sup> Information in the “file path” field identifies the location in which an electronic file resided on Ethicon’s network system or a custodian’s work station at the time of collection. The file path information thus provides context and relationship information not otherwise available in internal document metadata fields. For example, from it a search can determine all documents a particular witness kept in the same folder.

<sup>2</sup> Plaintiffs issued separate discovery to Defendants Johnson & Johnson and Ethicon LLC. However, this Motion to Compel is directed solely at Ethicon, Inc.

of a discovery answer.” *Kelly v. FedEx Ground Package Sys.*, 3:10-cv-01265, 2011 U.S. Dist. Lexis 69972 (W.D. Va. June 29, 2011). Because plaintiffs have chosen to complain in the abstract rather than discuss the specifics that matter, their motion to strike “subject to” objections should be denied.

## **II. Ethicon Has Repeatedly Negotiated Exceptions to Its Objections to Foreign Regulatory and Foreign Entity Documents Based on Plaintiffs’ Stated Needs and Ethicon’s Burdens**

In the light of a year’s worth of negotiations, the production of regulatory documents from three countries the plaintiffs picked, the searches for regulatory documents from 32 countries, and the total of more than a million pages of foreign (and translated) documents produced, including worldwide adverse events, the plaintiffs’ claim that Ethicon has provided nothing more than “boilerplate” objections falls far short of the truth. Again, despite this production, plaintiffs do not offer even one example of relevant material they believe they have been denied. All too casually they dismiss both the legal irrelevance of their requests and the tremendous production burden they would impose. Their motion to strike “boilerplate” objections should be rejected for all of these reasons.

**Legal irrelevance.** Plaintiffs’ request for a global collection is particularly unreasonable given that foreign regulatory and marketing information is unlikely to be admissible in plaintiffs’ cases both because of its inherent irrelevance and likely confusion of issues. *See, e.g., Deviner v. Electrolux Motor AB*, 844 F.2d 769, 771 (11th Cir. 1988) (holding “Swedish standards are not relevant in a U.S. product liability case involving [products] sold in the U.S.”); *In re Viagra Prods. Liab. Litig.*, 658 F. Supp. 2d 950, 965 (D. Minn. 2009) (finding “any discussion of foreign regulatory actions . . . irrelevant to the current litigation” and excluding them under Rule 402 and 403); *In re Baycol Prods. Litig.*, 532 F. Supp. 2d 1029, 1054 (D. Minn. 2007) (excluding

foreign regulatory evidence because “allowing the admission of evidence of foreign regulatory actions, in a case that is governed by domestic law, would likely cause jury confusion”). Though Ethicon acknowledges that discoverable evidence is not coextensive with admissible evidence, it is equally well settled that “[t]he legal tenet that relevancy in the discovery context is broader than in the context of admissibility should not be misapplied so as to allow fishing expeditions in discovery.” *Piacenti v. Gen. Motors Corp.*, 173 F.R.D. 221, 226 (N.D. Ill. 1997).

**Ethicon’s response has not been “boilerplate.** Ethicon’s extensive production of foreign documents is discussed in the Declaration of Pamela Downs which is Exhibit D to this response. In summary, it includes:

- World-wide adverse event reports for the products at issue. (*Id.*)
- Both large groups of documents (e.g., the custodial files of approximately 52 ex-U.S. custodians which include nearly 250,000 pages of documents), and also specific categories requested by plaintiffs’ counsel.<sup>3</sup>
- Regulatory documents from three countries selected by the plaintiffs: Japan, France and Australia. This process required extensive communications with individuals in those countries and costly translations.
- Unique marketing materials for 32 separate countries, all of which are generally stored in their country of origin.

For this reason, AMS MDL’s Pretrial Order #24 is inapplicable here. (Motion to Compel, p. 9 (citing PTO-24, No. 2:12-md-2325 (S.D. W.V. Oct. 30, 2012))). In the AMS litigation, AMS’

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<sup>3</sup> These include the International Regulatory SharePoint (used by U.S. Regulatory Affairs to communicate with international employees regarding international regulatory filings); the Agile IFU repository; the GGM Blue marketing repository; the custodial files of the Europe, Middle East and Africa Marketing Manager and the Latin America Marketing Managers; and Investigatory Studies and product registries maintained in the United Kingdom.

apparent position was that no ex-U.S. documents should be produced. Ethicon has imposed no such restriction.

Even though plaintiffs' counsel have all of this information at their disposal, their motion wholly fails to identify any further foreign documents they believe are relevant and needed for this litigation.

**Undue burden.** Ethicon has retained an expert witness to testify under Rule 30(b)(6) about the existence and location of foreign documents and the burden required to produce them. If there were any questions about what Ethicon has withheld, presumably she could answer them. But, once again, instead of taking a deposition about the actual facts, plaintiffs have chosen to file an abstract motion based on a hypothetical state of affairs unrelated to the real world.

Attached as Exhibit D to this response is an affidavit by that witness, Pamela Downs, a Senior Director for Epiq Systems, Inc. for Litigation and eDiscovery Solutions. She has found that, among other things:

- Ethicon documents exist in potentially 190 countries;
- Some 67 countries regulate the Ethicon products that are at issue;
- Relevant documents are generally kept in the respective countries and are scattered among various custodians in each country;
- Each foreign language document would have to be translated; and
- In general, any modifications among documents used from one country to another are slight.

*See Ex. D.*

For these reasons, this Court should deny plaintiffs' request to strike Ethicon's objection to the production of foreign regulatory and other foreign documents. Plaintiffs have wholly

failed to prove, and they cannot prove, that Ethicon's response has been mere "boilerplate." At a minimum, Plaintiffs should be ordered to continue the extensive meet and confer that has attended this issue.<sup>4</sup>

### **III. Ethicon Has Provided an Attorney-Client Privilege Log and Has Not Withheld Confidential Documents**

Plaintiffs are simply incorrect in their assertion that privilege logs have not been produced. In fact, Ethicon has complied with Pre-Trial Order #13 and produced an extensive privilege log comprised of more than 18,000 documents. Accordingly, this part of plaintiffs' motion should also be denied.

Ethicon has provided both a privilege and redaction log. The privilege log contains the Bates ranges for privileged materials, the date, source, department, the "to" field, the "from" or author field, any carbon copies or blind carbon copies, the document type or subject, the privilege reason, the privilege description, and a narrative describing the redaction. The contents of the privilege log have been the subject of ongoing meet-and-confers between Ethicon, the plaintiffs, and their consultants. *See* Apr. 2, 2013 letter from B. Watson to consultant A. Irpino, Ex. E.

Because Ethicon has produced the required log, it has not waived any work product or attorney-client privilege or trade secret protection. *First Sav. Bank, F.S.B. v. First Bank Sys., Inc.*, 902 F. Supp. 1356, 1361 (D. Kan. 1995) ("As the federal rules, case law and commentators suggest, waiver of a privilege is a serious sanction most suitable for cases of unjustified delay, inexcusable conduct, and bad faith.").

In addition, while it is true that a few of Ethicon's objections mention confidentiality, Ethicon informed opposing counsel after the protective order was entered that it was not

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<sup>4</sup> Ethicon reserves the right, should further production be ordered, to submit cost evidence to the court that would justify cost-shifting as provided for in Fed. R. Civ. P. 26(b)(2)(B).

withholding documents on grounds of confidentiality, and it has not done so. See Feb. 15, 2013 email, Ex. C.

**IV. Ethicon Has Produced the Documents With an Electronically-Searchable ESI “Directory” Pursuant to a Protocol of the Plaintiffs’ Own Design.**

Ethicon has produced an ESI directory of documents that is electronically searchable and in a format agreed upon – nay, insisted upon – by the plaintiffs. With their Rule 33 responses, Ethicon referred to this directory. Plaintiffs’ motion to compel does not mention this directory or in any way describe how it is now thought to be inadequate or unresponsive to their queries.

Plaintiffs do not contend that the ESI directory is improperly produced pursuant to Rule 34. Thus, there is no claim that they would be burdened by searching the materials for the responses to their interrogatories. “The principle behind Rule 33(d) is that the interrogating party should bear the burden of gathering information . . . when the burden . . . would be the same for either party.” *Minter v. Wells Fargo Bank, N.A.*, 286 F.R.D. 273, 277 (D. Md. 2012) (citation and quotation marks omitted). “Rule 33 production is suited to those discovery requests requiring compilation or analysis, accomplished as easily by one party as another, or where neither side has clear superiority of knowledge or familiarity with the documents. Accordingly, Rule 33 is well-suited to reply to inquiries of an intensely objective nature.” *United Oil Co. v. Parts Assocs., Inc.*, 227 F.R.D. 404, 419 (D. Md. 2005).

The cases on which the plaintiffs rely are not cases in which the documents were provided in an electronic format with more than 30 identifying fields. *See, e.g., The Little Hocking Watter Ass’n, Inc. v. E.I. Du Pont de Nemours & Co.*, No. 2:09-cv-1081, 2013 U.S. Dist. LEXIS 22374 (S.D. Oh. Feb. 19, 2013) (denying motion to compel where “considering the broad scope of these interrogatories, [Defendant’s] narrative answers and reliance on documents (provided in a searchable format) pursuant to Rule 33(d) are sufficient”); *United States v. Rachel*,



289 F. Supp. 2d 688, 693 (D. Md. 2003) (Rule 33(d) response proper where “interrogatories were extremely broadly worded”); *Berster Techs., LLC v. Christmas*, 2:11-cv-1541-KJM-JFM 2011 U.S. Dist. LEXIS 114499 (E.D. Cal. Oct. 3, 2011) (motion to compel denied where Rule 33 directory was “in electronic format and, as proven by plaintiff’s own conduct, relatively easily searchable and, thus, not unduly burdensome”).

While discussing the indexing issue, the only specific response plaintiffs cite as deficient is the response to Interrogatory No. 16. To understand that, it is necessary to first consider Interrogatory No. 15, which asks:

When did You acquire information that provided evidence of a reasonable association between Pelvic Mesh Products and any Complications[?]

This interrogatory was fully answered. World-wide adverse event reports have been supplied. Plaintiffs do not complain about that answer.

Plaintiffs’ Interrogatory No. 16 asks, “When did You acquire information that provided evidence of a causal association between Pelvic Mesh Products and any Complications[?]”

Ethicon’s full response to this Interrogatory was:

Ethicon objects to Interrogatory No. 16 because, as worded it is ambiguous, overly broad, unduly burdensome and seeks information not reasonably calculated to lead to evidence admissible at trial. Ethicon further objects to the interrogatory because, as phrased, it assumes a “causal association” exists. Subject to and without waiving the foregoing Objections, Ethicon states that any such evidence if it exists would be equally available to Plaintiffs in the form of data from published studies regarding the Pelvic Mesh Products. Ethicon also refers to its Response to Interrogatory 15.

Interrogatory No. 16 is a classically bad interrogatory because of its use of the words “information” and “evidence.” When the Interrogatory’s complicated language is parsed, it turns out that the language merely duplicates its predecessor. In its prior response, Ethicon has already

identified “evidence” of “associate[ed]” complications. Any “evidence” of such a complication could also be taken by some as “evidence” of a “causal” association. To the extent the interrogatory might be taken to ask about actual causation, that is a matter of opinion from case to case. The best “evidence” would come from the published studies on which Ethicon relied when it sold the products. Those studies have dates, and plaintiffs’ counsel are well aware of them.

#### **V. Plaintiffs’ Miscellaneous Arguments Are Without Merit**

Plaintiffs’ remaining arguments regarding the “miscellaneous objections” are likewise without merit, as Plaintiffs fail to show how the extensive discovery obtained via the agreed-upon protocol is unresponsive or deficient in any way.

**Core Data Sheets.** First, Plaintiffs take issue with “undefined words or phrases” but point the Court only to a single example, the term “Core Data Sheets.” Though plaintiffs contend that this is “one of the most fundamental internal company documents,” that is not the case. While a “core data sheet” is a term and concept commonly used in the *pharmaceutical* industry, it does not have such a well-defined meaning or established use in the *device* industry. Accordingly, the term “core data sheet” is not well understood in this industry and it is a confusing request as stated. In any event, plaintiffs have failed to meet and confer regarding what information they require that has not been provided.

**Time period.** In addition, plaintiffs allege that Ethicon has improperly objected on the basis that the requests were not limited to any relevant time period (Motion to Compel, p. 14.) To be clear, Ethicon has produced available relevant documents dating from before and after 1998, when the first product at issue in this MDL was introduced. And contrary to plaintiffs’ contention, Ethicon’s responses do make clear why for certain products a time period is more

limited. In its response to Interrogatory No. 2, Ethicon stated that “For TVT IFUs in use prior to 1/16/2001, Ethicon states that a third party, Medscand Medical AB, not Ethicon, manufactured the device prior to that date and thus Ethicon did not generate the IFUs during that time period. Ethicon will update this response if a copy of the applicable IFU(s) is obtained.” In any event, plaintiffs have failed to complete the meet and confer process regarding what information they require that has not been provided.

**Equal access.** Plaintiffs further argue that Ethicon’s “equal access” objections were improper. Again, plaintiffs fail to show that they did not obtain the information sought or that they met and conferred to try to obtain what they were lacking. Indeed, Request for Production No. 47 shows the propriety of the objection. Request for Production No. 47 requests “All scientific, clinical, and medical literature in YOUR possession, custody or control concerning the safety and/or efficacy of Pelvic Mesh Products or Hernia Mesh Products.” Ethicon responded:

Ethicon objects to this request on the grounds that it is overbroad, unduly burdensome, vague, ambiguous and confusing. Ethicon further objects to this request on the ground that it seeks the production of documents that are neither relevant nor reasonably calculated to lead to the discovery of admissible evidence, particularly as directed to hernia mesh products. Ethicon objects as unduly burdensome to the production of documents that are equally available to the Plaintiffs in the public domain. Consistent with the Federal Rules, and the Protective Order entered by the Court, documents responsive to this Request, if they exist, have been or will be produced to Plaintiffs in the manner in which they were kept in the ordinary course of business. The electronic production is in searchable format and, as such and consistent with the Federal Rules, Plaintiffs can locate the particular electronic documents responsive to this Request.

Ethicon has conducted a reasonable search and has already produced relevant scientific, clinical, and medical literature totaling approximately 16,000 documents. Plaintiffs’ request thus demands Ethicon to produce to them again that literature which “concern[s]” safety or efficacy. Clearly, any responsive scientific, clinical, and medical literature concerns safety and efficacy in

some way. Plaintiffs' request that Ethicon make some interpretation as to what "safety and/or efficacy" is presumed to mean in order to narrow down the literature is vague and improper. Again, plaintiffs have failed to meet and confer regarding what information they require that has not been provided.

**Procedures.** Finally, plaintiffs' objection to Ethicon's response to Request for Production No. 5 again neglects the extensive history of communications between the parties regarding this issue. (Motion to Compel, p. 15-16.) This Request is for "All DOCUMENTS that reflect the policies and procedures that Defendants has had and/or has in place for the storage, deletion, and back-up of DOCUMENTS and emails generated by Defendants' employees and agents." Ethicon objected in part based on "undue burden and cost." Plaintiffs' description of this response simplifies the issue to the point of obfuscation.

Ethicon did not merely respond that the information was unduly burdensome and refuse to produce. Rather, Ethicon's undue burden objection was solely based on the production of materials not maintained in the active working environment.<sup>5</sup> See Supp. Response to Request for Prod. No. 5. It is estimated that the total volume of policies and procedures is approximately 100,000 documents with an additional 500,000 revisions. Ethicon used search terms and produced a spreadsheet of 800 company procedures. Plaintiffs selected 171 and Ethicon produced them as well as all prior versions and revision histories. To the extent additional information is sought, Ethicon has been and remains open to meeting and conferring on this issue

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<sup>5</sup> The discovery response states: "Ethicon objects to the production of documents relating to network infrastructure, backup tapes, and backup policies and schedules and network retention policies, as well as electronically archived materials not maintained in active working environments. Ethicon objects to the production of such information as impermissible 'discovery on discovery.' Further, Ethicon's backup tapes are used solely for disaster recovery and not for archival or active storage purposes. Discovery of such data is not reasonably accessible because of the undue burden and cost that would be involved and is therefore protected from disclosure."

to reach a mutually acceptable resolution. Ethicon further has specifically requested that this matter be discussed between the parties' respective technical experts. *See* Ex. F; Ex. G.

### **CONCLUSION**

The Court should consider the positions of the parties and deny the motion to compel in its entirety.

Ethicon has met, has conferred, and has even offered Rule 30(b)(6) witnesses.

Plaintiffs' counsel have refused to fully confer on general objections, have acted as if no foreign documents or privilege log had ever been supplied, have refused proffered witnesses, and have failed to say why the ESI system they helped design is inadequate.

This Court should not place further discovery burdens on the shoulders of Ethicon when plaintiffs' counsel refuse to lift a finger to accept the help Ethicon has offered, i.e., to engage in a question by question meet and confer as requested by Ethicon. Accordingly, Plaintiffs' motion to compel should be denied and the Court should order the parties to continue to meet and confer to quickly resolve their differences.

Dated: June 3, 2013

Respectfully submitted,

/s/ Christy D. Jones

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**CERTIFICATE OF SERVICE**

I hereby certify that on June 3, 2013, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to CM/ECF participants registered to receive service in this MDL.

*Christy D. Jones*

Christy D. Jones

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